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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Group Art Unit 1614

Patent Application of  
Joyce C. Knutson, et al.  
Application No. 10/766,749  
Confirmation No.: 3650  
Filed: January 28, 2004  
Examiner: Not Known

I, Sally Sorensen, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

Sally Sorensen  
Signature

September 15, 2004  
Date of Signature

METHOD FOR TREATING AND PREVENTING SECONDARY  
HYPERPARATHYROIDISM

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 CFR §1.97(b)(3)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

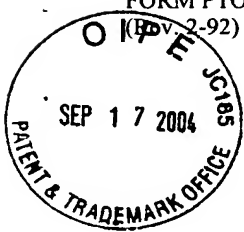
The Examiner's attention is directed to the references listed on the attached Form PTO-1449. Copies of all foreign and non-patent references are enclosed. In accordance with the waiver of 37 CFR 1.98(a)(2)(i) regarding U.S. patents, copies of the patent references are not enclosed as the above-identified patent application was filed after June 30, 2003.

In accordance with 37 CFR 1.97(b)(3) these references are provided before the mailing of a first Office Action on the merits. Citation of these references is respectfully requested. No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted,

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**File No. 017620-9381**  
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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Rev. 2-92) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT:

(Use several sheets if necessary)

ATTY. DOCKET NO.: 017620-9381  
SERIAL NO.: 10/766,749  
APPLICANT: Joyce C. Knutson.  
FILING DATE: January 28, 2004  
GROUP: 1614

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	APPLICANT	CLASSIFICATION
	2,383,446	6/1941	Calcott <i>et al.</i>	
	3,697,559	10/1972	DeLuca <i>et al.</i>	
	3,741,996	6/1973	DeLuca <i>et al.</i>	
	4,160,803	7/1979	Potts	
	4,341,774	7/1982	Aoki <i>et al.</i>	
	4,362,710	12/1982	Watanabe	
	4,388,243	6/1983	Nishikawa <i>et al.</i>	
	4,391,802	7/1983	Suda <i>et al.</i>	
	4,508,651	4/1985	Baggiolini <i>et al.</i>	
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	4,661,294	4/1987	Holick <i>et al.</i>	
	4,670,190	6/1987	Hesse <i>et al.</i>	
	4,689,180	8/1987	DeLuca <i>et al.</i>	
	4,698,328	10/1987	Neer <i>et al.</i>	
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	4,902,481	2/1990	Clark <i>et al.</i>	
	4,929,610	5/1990	Meier, <i>et al.</i>	
	4,948,789	8/1990	Slatopolsky	
	5,035,783	7/1991	Goethals <i>et al.</i>	
	5,098,899	3/1992	Gilbert <i>et al.</i>	
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	5,190,935	3/1993	Binderup <i>et al.</i>	
	5,205,989	4/1993	Aysta	
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	5,264,184	11/1993	Aysta <i>et al.</i>	

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	5,264,618	11/1993	Felgner <i>et al.</i>	
	5,304,291	4/1994	Bout <i>et al.</i>	
	5,334,740	8/1994	Takahashi <i>et al.</i>	
	5,338,532	8/1994	Tomalia <i>et al.</i>	
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	5,665,387	9/1997	Mathieu <i>et al.</i>	
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	5,707,980	1/1998	Knutson <i>et al.</i>	
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	5,739,271	4/1998	Sridhar <i>et al.</i>	
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	5,750,746	5/1998	DeLuca <i>et al.</i>	
	5,756,783	5/1998	Knutson <i>et al.</i>	

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	5,795,882	8/1998	Bishop <i>et al.</i>	
	5,869,473	2/1999	Knutson <i>et al.</i>	
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	6,376,479	4/2002	Knutson <i>et al.</i>	
	6,521,608	2/2003	Henner <i>et al.</i>	
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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
				YES	NO
	EP 0 503 630 A1	9/1992	Europe		
	EP 0 562 497 A1	9/1993	Europe		
	EP 0 664 287 B1	7/1995	Europe		
	EP 0 197 514 A1	10/1986	Europe		
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	EP 0 381 750 B1	8/1990	Europe		
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	NZ 316662	3/2001	New Zealand		
	WO 84/04527	11/1984	PCT		
	WO 90/01321	2/1990	PCT		
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	WO 92/12165	7/1992	PCT		
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	WO 94/00128	1/1994	PCT		
	WO 94/05630	3/1994	PCT		
	WO 94/16711	8/1994	PCT		
	WO 96/31215	10/1996	PCT		
	WO 96/40154	12/1996	PCT		
	AU 634490	6/1993	Australia		
	JP 6025039	2/1994	Japan	English Abstract	X
	JP 62000033	1/1987	Japan	English Abstract	X
	JP 5320127	12/1993	Japan	English Abstract	X

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
		HU 207040 B	3/1993	Hungary	English Abstract of EP equivalent	X
		HU 2307/90 A	9/1991	Hungary	Coverpage	X
		BE 877 356	10/1979	Belgium		X
		EP 0390097	10/1990	Europe		
		WO 87/00834	12/1987	PCT		
		WO 90/10620	9/1990	PCT		
		WO 92/21355	12/1992	PCT		
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AB	Abbott Laboratories, Kidney Disease (1/29/03) <a href="http://abbot.com/disease/kidney_disease.htm">http://abbot.com/disease/kidney_disease.htm</a>
AC	Acchiardo, Sergio R., <i>et al.</i> , Efficacy of Pulse Dose Oral 1 <sub>α</sub> -Hydroxyvitamin D <sub>2</sub> (1 <sub>α</sub> -OH-D <sub>2</sub> ) as a Therapy for Secondary Hyperparathyroidism (HPT) in Hemodialysis (HD) Patients (PTS), Abstract Presented at the American Society of Nephrology, November 2-5, 1997, San Antonio, Texas
AD	Aubia, J., <i>et al.</i> , <i>Proc Eur Dial Transplant Assoc Eur Ren Assoc</i> , 21:902-908 (1985) PMID 3991589 Abstract
AE	Avioli, L., <i>Calcif. Tissue Int.</i> 65:292-294 (1999)
AF	Barton, D. <i>et al.</i> , "Synthetic Uses of Steroidal Ring & Diene Protection: 22,23-Dihydroergosterol," <i>JCS Perkin I</i> , (1976) pp. 821-826.
AG	BeActive: About Chronic Kidney Disease, 1/29/03, <a href="http://beactive.com/aboutckd">http://beactive.com/aboutckd</a>
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AI	Beer, <i>et al.</i> , "Weekly High-Dose Calcitriol and Docetaxel in Advanced Prostate Cancer," <i>Seminars in Oncology</i> , Suppl 15 (August 2001) 28:4:49-55.
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AK	Bischoff, H.A. <i>et al.</i> , <i>Arch. Phys. Med. Rehabil.</i> 80:54-58 (1999).
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AM	Blazsek, I. <i>et al.</i> "Combined Differentiation Therapy in Myelodysplastic Syndrome with Retinoid Acid, 1 $\alpha$ ,25 Dihydroxyvitamin D <sub>3</sub> , and Prednisone," <i>Cancer Detect. Prev.</i> (1992) 16:4:259-264.
AN	Braunwald, E. <i>et al.</i> , <i>Harrison's Principles of Internal Medicine</i> : Part Eleven, "Disorders of Bone and Mineral Metabolism," Chapter 335, McGraw-Hill, New York, (1987) pp. 1860-1865.
AO	Brautbar, N. "Osteoporosis: Is 1,25-(OH)2D3 of Value in Treatment?" <i>Nephron</i> (1986) 44:161-166.
AP	BROWN, C. <i>et al.</i> , Revisiting Hypocalciuria of Early Chronic Renal Insufficiency (CRI), Abstract Presented at the American Society of Nephrology, November 1999, Miami, Florida.
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AT	Chapuy, M.C. and Meunier, P.J., "Vitamin D insufficiency in adults and the elderly", <i>Vitamin D</i> , Feldman D, Glorieux FH, Pike JW (eds) Academic Press, San Diego, CA pp. 679-693 (1997)
AU	Chesney, R.W., <i>et al.</i> , 1 $\alpha$ Hydroxyvitamin D <sub>2</sub> (1-OH-D <sub>2</sub> ): Initial Results from U.S. Phase 3 Trials in Hemodialysis Patients with Secondary Hyperparathyroidism, Abstract Presented at the XXXV Congress of the ERA-EDTA European Renal Association, September 21-24, 1997, Jerusalem, Israel.
AV	Cho, Y.L. <i>et al.</i> , "Combined Effects of 1,25-Dihydroxyvitamin D <sub>3</sub> and Platinum Drugs on the Growth of MCF-7 Cells," <i>Cancer Research</i> , (June 1991) 51:2848-2853.
AW	Christiansen, C. <i>et al.</i> , "Prevention of Early Postmenopausal Bone Loss: Controlled 2-Year Study in 315 Normal Females," <i>Europ J Clin Inves.</i> , (1980) 10:273-279.
AX	Civitelli, R., <i>Calcif. Tissue Int.</i> 57:409-414 (1995)
AY	Coburn, J.W. <i>et al.</i> , Use of Intravenous 1 $\alpha$ -Hydroxyvitamin D <sub>2</sub> in Hemodialysis Patients with Moderate-to-Severe Secondary Hyperparathyroidism, Abstract Presented at the 1998 Joint Meeting of the ASBMR and the International Bone & Mineral Society, December 1-6, 1998, San Francisco, California.
AZ	Coburn, J.W., <i>et al.</i> , 1 $\alpha$ -Hydroxy-Vitamin D <sub>2</sub> (1-OH-D <sub>2</sub> ) Suppresses PTH Safely in Dialysis Patients with Secondary Hyperparathyroidism, Abstract Presented at the International Symposium on Advances in Renal Osteodystrophy, March 1997, Oviedo, Spain.

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BA	Coburn, J.W., <i>et al.</i> , Effect of Severity of Secondary Hyperparathyroidism on the Response to $1\alpha$ Hydroxyvitamin D <sub>2</sub> ( $1\_D_2$ ) IN Hemodialysis Patients, Abstract Presented at the International Congress of Nephrology, May 2-6, 1999, Buenos Aires, Argentina.
BB	Coburn, J.W., <i>et al.</i> , Hyperphosphatemia Impairs the Suppression of Intact PTH by Treatment with $1\alpha$ Hydroxyvitamin D <sub>2</sub> in Secondary Hyperparathyroidism: A Prospective, Controlled Study, Abstract Presented at the Official Satellite Symposium, May 7-9, 1999, Iguazu Falls, Brazil.
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BE	Crump, D.R. <i>et al.</i> , "(22S)-Hydroxyvitamin D <sub>4</sub> ," <i>J.C.S. Perkins Trans. I</i> , (1973) pp. 2731-2733.
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BG	DeChant, K.L. and Goa, K.L., <i>Drugs &amp; Aging</i> , 5(4):300-317 (1994)
BH	Defacque, H. <i>et al.</i> , "Different Combinations of Retinoids and Vitamin D <sub>3</sub> Analogs Efficiently Promote Growth Inhibition and Differentiation of Myelomonocytic Leukemia Cell Lines," <i>J. Pharmacology and Experimental Therapeutics</i> , (1994) 271:193-199.
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BJ	Douthat, W.G., <i>et al.</i> , Treatment of refractory secondary hyperparathyroidism with ethanol injection: The importance of glandular volume, <i>Kidney Intl.</i> 63:85:S101-S104
BK	Drueke, T.B., Control of Secondary Hyperparathyroidism by Vitamin D Derivatives, <i>American Journal of Kidney Diseases</i> . 37:1 [Suppl 2] (Jan 2001) S58-S61.
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

BM	Duda <i>et al.</i> , "1,25-Dihydroxyvitamin D Stimulation Test for Osteoblast Function in Normal and Osteoporotic Postmenopausal Women," <i>J. Clinic Inves.</i> , (1987) 79:1249-1253.
BN	Eastell, R and Roggs, B.L., "Vitamin D and osteoporosis", <i>Vitamin D</i> , Feldman D, Glorieux FH, Pike JW (eds) Academic Press, San Diego, CA pp. 695-711 (1997)
BO	Endo, K. <i>et al.</i> , "Effect of Combination Treatment with Vitamin D Analog (OCT) and a Bisphosphonate (AHPBP) in a Nude Mouse Model of Cancer-Associated Hypercalcemia," <i>Journal of Bone and Mineral Research</i> , (1998) 13:9:1378-1383.
BP	Engstrom, G.W. <i>et al.</i> , <i>Archives of Biochemistry and Biophysics</i> 270(2) 432-440 (May 1, 1989)
BQ	Foldes, J. <i>et al.</i> , "Long Term Treatment with 1 $\alpha$ (OH)D <sub>3</sub> for Postmenopausal Osteoporosis: Efficacy and Safety," <i>Osteoporosis</i> , (1987) 2:971-973.
BR	Francis, R.M. <i>et al.</i> , <i>Osteoporosis Int.</i> 6:284-290 (1996)
BS	Francis, R.M., <i>Calcif. Tissue Int.</i> 60:111-114 (1997)
BT	Frazao, <i>et al.</i> , Use of 1 $\alpha$ Hydroxyvitamin D <sub>2</sub> (1-D <sub>2</sub> ) in 121 Hemodialysis Patients with Secondary Hyperparathyroidism: A Phase 3 Trial, Abstract Presented at the American Society of Nephrology, November 2-5, 1997, San Antonio, Texas.
BU	Frazao, J.M. <i>et al.</i> , Comparison of Intravenous with Oral 1 $\alpha$ Hydroxyvitamin D <sub>2</sub> (1-D <sub>2</sub> ) in Hemodialysis Patients with Secondary Hyperparathyroidism, Abstract Presented at the American Society of Nephrology, October 25-27, 1998, Philadelphia, Pennsylvania.
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ATTY. DOCKET NO.: 017620-9381  
SERIAL NO.: 10/766,749  
APPLICANT: Joyce C. Knutson.  
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GROUP: 1614

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT:

(Use several sheets if necessary)

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

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	GP	Martin and DeLuca, "Influence of sodium on calcium transport by the rat small intestine" <i>Am. J. Physiol.</i> , 216(6):1351-1359 (1969).
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